

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

_____)	
DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation)	
)	
Defendant.)	
_____)	

DEFENDANTS ARTHREX, INC.'S AND PEARSALLS, LTD.'S
CONCISE STATEMENT OF MATERIAL FACTS IN SUPPORT OF THEIR MOTION
FOR SUMMARY JUDGMENT

Pursuant to Rule 56.1 of the Local Rules, District of Massachusetts, Defendants Arthrex, Inc. ("Arthrex") and Pearsalls, Ltd. ("Pearsalls") (together, "defendants") hereby submit their concise Statement of Material Facts in Support of their Motion for Summary Judgment against plaintiff DePuy Mitek, Inc. ("DePuy Mitek"):

1. Plaintiff Depuy Mitek, a Massachusetts corporation, and a Johnson & Johnson company, makes and sells medical products. Ex. 17.¹
2. Defendant Arthrex, a privately held Delaware corporation, develops and sells medical products in the field of arthroscopic surgery. FiberWire suture and its related products TigerWire and FiberStick ("collectively "FiberWire") are among those products and are the ones accused of infringement of U.S. Patent No. 5,314,446 ("the '446 patent"). Ex. 16.

¹ Except where otherwise indicated, "Ex." refers to Exhibits to the Memorandum in Support of Defendants Arthrex, Inc.'s and Pearsalls, Ltd.'s Motion for Summary Judgment.

3. Defendant Pearsalls, a United Kingdom company, is a braid manufacturer which makes the braids that eventually become FiberWire suture.

4. Ethicon, a Johnson & Johnson company, is related to DePuy Mitek and the original owner of the '446 patent. Ex. 18.

5. In 2001, Arthrex introduced a new suture, called FiberWire, for the orthopedic surgery market. Ex. 1 at 31:2-5.

6. FiberWire was so new and revolutionary that it spawned a new category of suture called "high-strength" suture. Ex. 2 at 2; Ex. 4 at 146:7-14.

7. FiberWire suture was the first "high-strength" suture introduced into the market. Ex. 2 at 2; Ex. 4 at 146:7-14.

8. FiberWire was more than twice as strong as the sutures conventionally used in orthopedic surgery, including Ethibond, the leading suture for the orthopedic market sold by Ethicon. Ex. 2 at 8.

9. FiberWire obtains its strength because it contains ultra high molecular weight polyethylene ("UHMWPE"), one of the strongest synthetic materials ever created.. Ex. 3 at § 1.

10. After seeing the impact of FiberWire, DePuy Mitek realized that without the introduction of its own high strength suture, it would not be able to meet its sales targets. Ex. 5.

11. DePuy Mitek's original idea was to introduce a "me too" suture that mimicked FiberWire. Ex. 5. In late 2004, DePuy Mitek introduced its own high strength suture called Orthocord, which also includes UHMWPE. Ex. 6.

12. Shortly before filing this lawsuit, the '446 patent was assigned from Ethicon to DePuy Mitek. Ex. 7. In this lawsuit, DePuy Mitek alleges that defendants infringe claims 1, 2, 8, 9 and 12 of the '446 patent ("the asserted claims").

13. Neither Ethicon, nor DePuy Mitek has never made a commercial product covered by the '446 patent. The '446 patent is a paper patent. Ex. 9.

14. Ethicon began the work that led to the '446 patent in 1988. As explained by inventor Steckel, this work was part of a larger project designed to examine possible suture improvements. Ex. 19 at 103:23-104:17.

15. At the time, a standard braided suture was Ethibond, a suture made entirely of PET polyester, which was braided to form the suture. Ex. 4 at 135:4-7.

16. Dr. Steckel's idea was to braid together two different substances, one to maintain as much of the strength of the suture as possible and the other to enhance the pliability (that is, bendability) and handleability of the suture. As Dr. Steckel explained, the goal was to produce a suture which maintained the strength of Ethibond (made of PET), while having the feel and pliability of silk, a substance known to be very pliable and easy to use. Ex. 19 at 103:23-104:17.

17. Ethicon built and test heterogeneous braids, made of PTFE and PET, by February 2, 1989. None of these braids, however, were sterilized. Ex. 19 at 225:5-8.

18. Ethicon never built a sterilized surgical suture that included all the limitations of the asserted claims before the filing date of the '446 patent. Ex. 10 at 346:7-10.

19. During his development work, Dr. Steckel observed that the prototype composite braid "ranked better than the silk and Ethibond in knot tie-down even without a coating." Ex. 21 at DMI 2666.

20. Dr. Steckel knew during the development work that lead to the '446 patent that UHMWPE had great strength. Ex.5 (to *Markman* Brief) at 190:12-191:3.

21. Ethicon filed the application that led to the '446 patent on February 19, 1992, three years after Dr. Steckel tested the braids. Ex. 8 at cover page.

22. The specification of the '446 patent begins with a summary of prior suture development, explaining that multi-filament braided sutures were developed to improve suture pliability compared to monofilament, unbraided sutures. Ex. 8 at col. 1, ll. 5-25.

23. The specification cautioned that mechanisms, such as coating, will adversely affect braid mobility and explained that "the prior art abounds with attempts to improve specific properties of multifilament braids at the expense of restricting the movement of adjacent filaments which make up the braid." Ex. 8 at col. 1, ll. 26-29.

24. The first example presented in the specification is coating, which "improve[s] handling properties," but at the expense of braid pliability. Ex. 8 at col. 1, ll. 29-31.

25. The specification suggests that while a braid made entirely of "highly lubricious polymers" can be used to make a highly pliable braid, such a braid "will be relatively weak and unusable. Hence, a tradeoff between braid strength and pliability exists in the design of conventional braided multifilaments." Ex. 8 at col. 2, ll. 22-28.

26. This theme that lubricious polymers are too weak for suture usage is repeated when the specification explains that a "volume fraction of lubricating yarns . . . above 80% may adversely affect the overall strength of the braid." Ex. 8 at col. 4, ll. 50-54.

27. The specification then explains that the proposed solution is to have a suture comprised of a heterogeneous braid made of two different fiber forming materials which exhibits "improved pliability and handling properties . . . without appreciably sacrificing" [the suture's] physical properties," (Ex. 8 at col. 2, lines 31-37), namely its "physical strength and knot security." Ex. 8 at col. 2, l. 66. This proposed solution is repeated throughout the specification. Ex. 8 at col. 2, ll. 62-66; col. 6, ll. 7-8.

28. The '446 patent specifically refers to "pliability" in connection with "resistance to bending," (Ex. 8 at col. 1, ll. 11-15, 24) and "bending rigidity," (Ex. 8 at col. 6, ll. 44-45, col. 8 at Table, ll. 44-46), which are the inverse of pliability.

29. A handling property specifically identified in the '446 patent is "knot tie down." Ex. 8 at col. 6, ll. 7-8.

30. The '446 patent relies on what is called the "rule of mixtures" to attempt to demonstrate that this combination is an improvement in the art. The point made by the inventors is that gains in pliability and handleability by using the combination of highly pliable and lubricious, but relatively weak, materials with a stronger material outweighs the loss of suture strength. Ex. 8 at col. 8, ll. 22, 35 and 38.

31. The specification also discusses the use of coating on sutures. It explains that coating, if desired, can be added "to further improve the handleability and knot tiedown performance of the braid." The specification also states that it is better if coating is not used, explaining that if the braid "possesses a significant [amount] of the lubricious yarns, the conventional coating may be eliminated saving expense as well as the associated braid stiffening." Ex. 8 at col. 6, ll. 5-17.

32. Seven polymers (PTFE, FEP, PFA, PVDF, PETFE, PP and PE) are identified as the yarns that are included for lubricity so as to improve the overall pliability of the braid. Ex. 8 at col. 4, ll. 11-27.

33. Three materials, PET, nylon and aramid, are identified as the ones that could be used for improving the strength of the braid. Ex. 8 at col. 4, ll. 35-40. The term PE is never associated with the "strength" yarns.

34. Claim 1 of the '446 patent is to a surgical suture "consisting essentially of" a heterogeneous braid of a first and second set of yarns in a sterilized and braided construction. Ex. 8 at claim 1.

35. The remainder of the asserted claims ultimately depend from claim 1. Ex. 8 at claims 2, 8, 9, 12.

36. Claim 1 defines the first set of yarns as one of PTFE, FEP, PFA, PVDF, PETFE, PP and PE – the same materials identified in the specification as being pliable and lubricious. The claim defines the second set of yarns as one of PET, nylon and aramid – the same materials identified in the specification as being added for improving the strength of the braid. Ex. 8 at claim 1.

37. As the application for the '446 patent was originally filed, there were two sets of claims – one set for heterogeneous braids and a second set for surgical sutures made from heterogeneous braids. Ex. 22.

38. Ethicon was required to elect which set of claims it wanted to prosecute. The election was required because the patent examiner observed that they were distinct sets of claims where one set – the heterogeneous braid claims – were an intermediate product that could be used to make surgical sutures (the second set of claims) as well as other products. Ethicon elected to pursue the surgical suture claims. Ex. 23.

39. As originally filed, the first suture claim required only that the sterilized suture be comprised of two dissimilar yarns in direct intertwining contact. The specific materials were not part of the claim and it did not include the "consisting essentially of" limitation. Ex. 22.

40. In the first Office Action, the examiner rejected the suture claims based on U.K. patent application no. 2,218312A to Burgess ("the Burgess application") (Ex. 8 to *Markman* Brief).

41. The Burgess application disclosed a fishing line made of a heterogeneous braid where the braid was made of UHMWPE and either nylon or polyester. Ex. 8 (to *Markman* Brief). The examiner rejected the suture claims, explaining that the requirements for fishing line were similar to those of suture. Ex. 23 at 4.

42. In distinguishing the '446 patent from the Burgess application, Ethicon responded that because of its braided construction, "the fishing line of Burgess would have poor knot strength properties." [Emphasis in original.] Ethicon explained that the Burgess braid combination would have poor knot strength properties because it included UHMWPE. Ethicon stated that UHMWPE "gives the line minimal stretchability." [Emphasis in original.] Ex. 24 at 2.

43. Ethicon further explained that "although this thread has great strength properties, it suffers from low elongation and, in turn, poor knot strength properties." [Emphasis in original.] Ethicon concluded that, as a result of the different requirements of fishing line and suture, one should not look to the fishing line art. Ethicon also told the Patent Office that "[e]ven if one were to look to the fishing line art [the UHMWPE/polyester or nylon combination – the fishing line are presented by the Burgess application], one would inevitably design an unacceptable suture." Ex. 24 at 3-4.

44. Later during prosecution, Ethicon made two amendments to the claims. First, it abandoned the broad claims that required only that that braid be made of two dissimilar materials. Ex. 25 at 1. The allowed claims were limited to so that the dissimilar materials had to be from the group of specifically-named materials. Ex. 25.

45. The first set of yarns are from a group consisting of PTFE, FEP, PFA, PVDF, PETFE, PP and PE. The second set of yarns were from the group consisting of PET, nylon and aramid. Ex. 25.

46. The preamble of the claims was also amended to change the term “comprising” to “consisting essentially of.” Ex. 25 at 1.

47. UHMWPE is a stiff material. It is not a pliable material. Ex. 11 at ¶ 56; Ex. 10 at 306:20-307:4.

48. General purpose PE has been used in sutures and other materials for decades and is established as a general purpose commodity polymer. Ex. 3 at § 1.

49. UHMWPE was introduced as in fiber form in 1985 and is considered a specialized high performance product. Ex. 3 at § 1.

50. General purpose polyethylene and UHMWPE are not substitutes for each other. Ex. 12 (to *Markman* Brief) at 22.

51. The key structural characteristics of UHMWPE and general purpose polyethylene, molecular weight and molecular structure very different. Ex. 3 at § 2.

52. UHMWPE has a molecular weight in the range of 1 to 5 million, whereas general purpose PE has a molecular weight in the range of 50,000 to several hundred thousand. Ex. 3 at § 2.

53. UHMWPE exhibits a much higher degree of crystalline orientation and crystalline content as compared with general purpose polyethylene. Ex. 3 at § 2.

54. DePuy Mitek’s expert, Dr. Hermes’ first impression when reading the ‘446 patent was that it “seem[ed] to teach away from UHMWPE.” Ex. 14 (to *Markman* Brief); Ex. 10 at 336:23-23.

55. Based on the teachings of the ‘446 patent, Ethicon’s statements in the prosecution history and the differences between general purpose polyethylene and UHMWPE, the term “PE” in the asserted claims of the ‘446 patent means general purpose polyethylene and does not include UHMWPE. Accordingly, FiberWire does not contain a material from the first set of

yarns and does not infringe the asserted claims of the '446 patent literally or by the doctrine of equivalents.

56. The specification of the '446 patent identifies the basic and novel characteristics of the claimed invention as being a suture having two dissimilar yarns (of the materials claimed) braided together to achieve improved handleability and pliability performance without significantly sacrificing its physical properties. This concept is repeated throughout the specification and is confirmed by the attorney who prosecuted the application for Ethicon and is consistent with Dr. Steckel's description of his work. Ex. 8 at col. 2, ll. 29 – 37; ll. 62 – 66; col. 4, ll. 11-40; col. 6, ll. 7 – 8; Ex. 8 at 110:14-20; Ex. 8 at 103:23—104:17.

57. Multiple patents, including patents owned by Ethicon and its expert, and publications (including from Ethicon) indicate that coating affects handleability characteristics of a suture, including knot tie-down. This was also asserted by Ethicon and DePuy Mitek when they developed suture products and was confirmed by several Ethicon and DePuy Mitek witnesses. Ex. 34, col. 1, ll. 14-18; Ex. 35, col. 1, ll. 11-15; Ex. 36, col. 1, ll. 12-15; Ex. 37, col. 1, ll. 19-25; Ex. 29 at 11; Ex. 28 at 525; Ex. 39; Ex. 40; Ex. 4 at 64:12-24; Ex. 41 at 48:11-49:2; Ex. 31 at 167:1-13; Ex. 18 at 295:23-296:7; Ex. 42 at 63:10-23; Ex. 14; Ex. 8 at col. 1, ll. 29-31; col. 6, ll. 5-8. As stated above, the '446 patent also states that coating improves the handling characteristics of the suture, including knot tie-down.

58. FiberWire contains a coating to improve handling characteristics, including suture slide, knot tying and ease of passing suture through tissue. Ex. 14.

59. For the reasons stated above, coating affect the basic and novel characteristics of the asserted claims of the '446 patent and its inclusion in FiberWire precludes infringement of those claims.

NOTE; THE REMAINING FACTS ARE SUBMITTED ONLY IF THE COURT CONSTRUES “PE” TO INCLUDE UHMWPE.

60. United States Patent No. 5,318,575 (“the ‘575 patent”) is prior art to the ‘446 patent. Ex. 15 at cover page; Ex. 8 at cover page.

61. Ethicon did not reduce to practice any product that included all the limitations of the asserted claims of the ‘446 patent before the filing date of the ‘446 because it never built a braid that was sterilized before the filing date, as shown above. “Sterilized” is a limitation of each asserted claim of the ‘446 patent. Ex. 8 at claim 1, 2, 8, 9, 12.

62. The ‘575 patent discloses every limitation of the asserted claims of the ‘446 patent. The ‘575 patent discloses a surgical suture. Ex. 15 at col. 2, l. 62; col. 3, ll. 2, 8, 15; col. 7, l. 26, 38, 43, 59; Ex. 10 at 212:25-213:5.

63. The ‘575 patent discloses a heterogeneous braid composed of a first and second set of continuous and discrete yarns in a sterilized, braided construction wherein at least one yarn from the first set is in direct intertwining contact with a yarn from the second set. Ex. 15 at col. 2, l. 65 – col. 3, l. 2; Ex. 10 at 170:6-12; Ex. 15 at claim 1.

64. FIG. 6 of the ‘575 patent discloses a spiroid braid with several yarns (items 26) that are braided in “direct intertwining contact.” Ex. 10 at 201:24-202:5.

65. The ‘575 patent discloses that one of the yarns braided together to form a suture is UHMWPE. Ex. 15 at col. 2, l. 31; Ex. 10 at 197:12-25

66. The ‘575 patent discloses that one of the yarns braided together to form a suture is PET or nylon. Ex. 15 at claim 11; claim 12; Ex. 10 at 198:7-11, 14-18.

67. The ‘575 patent discloses that the suture is attached to a needle. Ex. 15 at col. 5, ll. 41-42.

68. The '575 patent discloses that UHMWPE can be constitute a volume fraction in the braided sheath and core from about 20-80%. Ex. 15 at col. 4, ll. 8-24; Fig.6.

69. For these reasons, the '575 patent renders the asserted claims of the '446 patent invalid for anticipation.

Dated: August 11, 2006

Respectfully submitted,

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